

TABLE 9-continued

Characteristics of nude mice 50 days after subcutaneous inoculation of SCC-1 squamous carcinoma cells and treatment (i.p.) with OGF and/or paclitaxel				
Parameter	Controls	OGF	Paclitaxel	Paclitaxel/ OGF
Spleen Weight, mg	243 ± 25	25 ± 12	243 ± 8	197 ± 19
Metastases	none	none	none	none

Data represent means ± SEM.

N.A. = data not available because only one mouse was alive on day 50; spleen and body weights for the paclitaxel group only were calculated on the day each mouse died.

Significantly different from controls at $p < 0.05$ (*), $p < 0.01$ (**) and $p < 0.001$ (***).

Significantly different from OGF group at $p < 0.05$ (+) and $p < 0.001$ (+++).

Significantly different from the paclitaxel-treated mice at $p < 0.001$ (***).

TABLE 10

Receptor binding analysis of OGF in SCC-1 tumors from mice treated with OGF and/or paclitaxel.				
Parameter	Controls	OGF	Paclitaxel	Paclitaxel/ OGF
K_d , nM	1.0 ± 0.1	2.1 ± 0.3	1.2 ± 0.2	1.4 ± 0.3
B_{max} , fmol/mg protein	14.9 ± 1.2	27.2 ± 2.2*	27.8 ± 1.6*	20.5 ± 2.1

Data represent means ± SEM.

Significantly different from controls at $p < 0.05$ (*).

[0306] It should be understood that the embodiments described herein are for illustrative purposes only and that various modifications or changes in light thereof will be suggested to persons skilled in the art and are to be included within the spirit and purview of this application.

The invention claimed is:

1. A pharmaceutical composition for treating neoplasias in an animal or human which are characterized by an opioid growth factor receptor, comprising: therapeutically effective amounts of at least one chemotherapeutic, biotherapeutic, and/or radionuclide agent with opioid growth factor; and a carrier.

2. The pharmaceutical composition of claim 1 wherein said agent is a therapeutic agent.

3. The pharmaceutical composition of claim 2, wherein the neoplasias includes not limited to pancreatic cancer, squamous cell cancer of the head and neck, breast cancer, colorectal cancer, renal cancer, brain cancer, prostate cancer, bladder cancer, bone or joint cancer, uterine cancer, cervical cancer, endometrial cancer, multiple myeloma, Hodgkin's disease, non-Hodgkin's lymphoma, melanoma, leukemias, lung cancer, ovarian cancer, gastrointestinal cancer, Kaposi's sarcoma, liver cancer, pharyngeal cancer and laryngeal cancer.

4. The pharmaceutical composition of claim 3, wherein the chemotherapeutic agent is selected from but not limited to the group comprising: busulfan, cisplatin, carboplatin, chlorambucil, cyclophosphamide, ifosfamide, dacarbazine (DTIC), mechlorethamine (nitrogen mustard), melphalan, carmustine (BCNU), lomustine (CCNU), 5-FU, capecitabine, methotrexate, gemcitabine, cytarabine (ara-C), fludarabine, dactinomycin, daunorubicin, doxorubicin (Adriamycin), idarubicin, mitoxantrone, paclitaxel, docetaxel, etoposide (VP-16), vinblastine, vincristine, vinorelbine, prednisone, dexamethasone, tamoxifen, fulvestrant, anastrozole, letrozole, megestrol acetate, bicalutamide, flutamide,

leuprolide, goserelin, L-asparaginase, and tretinoin, gemcitabine, paclitaxel, carboplatin, and 5-FU.

5. The pharmaceutical composition of claim 4, wherein the therapeutic effective amount of OGF is about 100 to 400 µg/kg body weight when administered intravenously.

6. The pharmaceutical composition of claim 5, wherein the therapeutic effective amount of the chemotherapeutic agent ranges from about 100 to 1000 mg/m² when administered intravenously.

7. A method for treating neoplasias characterized by an opioid growth factor receptor in an animal or human in need of such treatment, comprising: administering to said animal or human therapeutically effective amounts of each of at least one neoplasia-treating agent and opioid growth factor.

8. The method of claim 7 wherein said neoplasia treating agent is radiation.

9. The method of claim 7 wherein said neoplasia treating agent is a biotherapy agent.

10. The method of claim 7 wherein said neoplasia treating agent is a chemotherapy agent.

11. The method of claim 7 wherein said neoplasia treating agent is a radionuclide.

12. The method of claim 7, wherein the opioid growth factor specifically binds to an opioid growth factor receptor.

13. The method of claim 7, wherein the neoplasias includes but is not limited to pancreatic cancer, squamous cell cancer of the head and neck, breast cancer, colorectal cancer, renal cancer, brain cancer, prostate cancer, bladder cancer, bone or joint cancer, uterine cancer, cervical cancer, endometrial cancer, multiple myeloma, Hodgkin's disease, non-Hodgkin's lymphoma, melanoma, leukemias, lung cancer, ovarian cancer, gastrointestinal cancer, Kaposi's sarcoma, liver cancer, pharyngeal cancer and laryngeal cancer.

14. The method of claim 7, wherein the neoplasia-treating agent is a chemotherapeutic agent including but is not limited to gemcitabine, paclitaxel, carboplatin, and 5-fluorouracil.

15. The method of claim 7, wherein the therapeutic effective amount of opioid growth factor administered is about 100 to 400 µg/kg body weight per day when administered intravenously.

16. The method of claim 7, further comprising: administering a chemotherapeutic agent sequentially or simultaneously with opioid growth factor in therapeutically effective amounts ranging from about 100 to 1000 mg/m² intravenously (OGF continuous treatment over a period of between about 10 to 60 minutes at least once a week for about three to ten weeks followed by a one to three week rest period; administering the chemotherapeutic agent at least once